DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 21, 2014

Virchow Biotech PVT LTD
% Bruce Gibbins, PhD.
5903 SE Milwaukie Avenue
Portland, Oregon 97202

Re: K132326
Trade/Device Name: Ionsil Gel™
Regulatory Class: Unclassified
Product Code: FRO
Dated: June 28, 2014
Received: July 23, 2014

Dear Dr. Gibbins:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

CONFIDENTIAL

510(k) Number:

Indications for Use Statement

Device Name: **IONSIL GEL™**

Indications for use:

OTC: For minor wounds, minor ulcerations, minor abrasions, minor surgical wounds and minor skin irritations.

Prescription Use_____ And/OR Over-The-Counter Use _X _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEAS DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

_____
(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number _____
Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary

5.1 Submitter's Name and Address

VIRCHOW BIOTECH PVT LTD
Plot No:318 & 320,
3rd Floor, Swamy Ayyapa Co-Op Housing Society Ltd.
Madhapur, Hyderabad
Telangana
India-500 081

Contact Person: Bruce Gibbins PhD
5903 SE
Milwaukie Avenue
Portland OR 97202
Ph No: +1 503 781 7565
Email: blgibbins@gmail.com

Date Prepared: **0**9 Aug 2014

5.2 Device Name

Trade Name: **IONSIL GEL™**

Common: Wound Hydrogel

Classification Name: Dressing, Wound and Burn, Hydrogel w/Drug and/or Biologic

Regulatory Class: Unclassified

Product Code: MGQ

5.3 Predicate Devices

IONSIL GEL™ is substantially equivalent to SilvaSorb Silver Antimicrobial Wound Gel /or (AKA) AcryDerm Silver Antimicrobial Wound Dressing (K011994).

5.4 Device Description

IONSIL GEL™ is a moist amorphous hydrophilic silver chloride gel designed to act as a barrier for wounds, as a moist wound dressing. The viscous hydrogel of the device contains silver in the form of silver chloride which acts as a self preservative that inhibits the growth of broad spectrum of micro organisms in the dressing.

The product is available in a 1.5 oz (45 gm) polyethylene heat sealed tube container. The tubes will be packed in a cardboard box.

5.5 Statement of Intended Use

IONSIL GEL™ is intended for OTC use in the management of normal skin and minor wounds, ulcerations, minor abrasions, minor surgical wounds and minor skin irritations.

5.6 Technological Characteristics and Substantial Equivalence

IONSIL GEL™ is essentially and substantially equivalent to the predicate device in its use for moist wound management. Both **IONSIL GEL**™ and **Acryderm Silver Antimicrobial Wound Gel** are offered as moist wound dressings in a tube**.** The technological characteristics of **IONSIL GEL™ and Acryderm Silver Antimicrobial Wound Gel** are substantially equivalent and both are indicated for use on minor wounds, minor ulcerations, minor surgical wounds, minor abrasions and minor skin irritations.

5.7 Assessment of Performance Data and Safety

Biocompatibility testing (systemic toxicity, cytotoxicity, sensitization and irritation) performed with **IONSIL GEL™** demonstrates that the dressing is safe for its intended use. The performed testing was conducted according to ISO Standards. *In vitro* antimicrobial testing was assessed by the standard Zone of Inhibition and USP Antimicrobial Effectiveness Test <51> and USP microbial limit test <61>